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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,720	10/29/2003	Stanley N. Cohen	FUNC-0027-CO5	3761

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EXAMINER	
YU, MISOOK	
ART UNIT	PAPER NUMBER
1642	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/697,720	COHEN ET AL.	
	Examiner	Art Unit	
	MISOOK YU	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-34* is/are pending in the application.

4a) Of the above claim(s) *31-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The review of the prosecution history indicates that claims 31-34 are presented with the amended filed on 02/26/2007 and the newly presented claims were withdrawn from the examination on merits in the Office action mailed on 04/19/2007 because the newly presented claims are drawn to two different inventions assigned as group II and III.

In the last non-final Office action mailed on 01/11/2009, the newly presented claims 31-34 were again assigned as group II and III respectively; however, this time, the reasons for the restriction between the elected group and the newly presented claims were different from those given in the earlier Office action.

Applicant argues that claims directed to an antibody to an antigen or complex comprising an antigen and an antibody would not impose an undue burden by requiring the examiner to perform a separate search of the prior art.

This argument has been fully considered but found unpersuasive because the elected invention is drawn to polypeptide and an antibody has different structure than the antigen it binds to and requires different search requiring different search query terms. While the elected polypeptide group, and the group III invention are comprised of amino acids, the elected polypeptide is a single chain molecule that functions as a potential transcription factor, whereas the polypeptide of group III encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold

for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group I and the antibody of group III are structurally distinct molecules; any relationship between a polypeptide of group I and an antibody of group III is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

Furthermore, searching the inventions of group I-III would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of group III. Furthermore, antibodies which bind to an epitope of a polypeptide of group I may be known even if a polypeptide of group I is novel. In addition, the technical literature search for the polypeptide, the antibody of group III or complex containing the two are not coextensive, e.g., antibodies or protein-antibody may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The requirement is still deemed proper and is therefore made FINAL.

Claims 31-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 04/14/2009. Claims 29-34 are pending. Claims 29-30 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

Applicants argues that the mere fact that the current application contains a 390 amino acid residue sequence, a sequence which is inherently the sequence of the isolated polypeptide of Example 1 of the specification as originally filed in 1995, does not impact priority if the claim does not require that 390 amino acid sequence for benefit.

This argument has been fully considered but found unpersuasive. The specification as originally filed in 1995 (US-08-585-758) does not disclose the protein inherently contains 390 amino acids. In order to practice the claimed invention, one of the skilled in the art has to know the 390 amino acids protein recited as SEQ ID NO: 4 in the instant claims 29 and 30. One of the skilled in the art looking at SEQ ID NO: 4 disclosed in US-08-585-758 would not be able to make a protein comprising the sequence of amino acids residues 11-390 of SEQ ID NO: 4 because the earlier application does not disclose a 390 amino acids protein.

Thus, the effective filing date of the claimed invention drawn to SED ID NO: 4 is10/29/2003.

Claim Rejections - 35 USC § 102

Claims 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Accession No U8213 (04-Jun-1998).

The Office agrees with applicant's statement that (1) US-08-585-758 (now US pat, 5,679,523) with 1996 filing date discloses SEQ ID NO: 4 with 10 amino acid residues missing at its N-terminal, otherwise identical to the instant SEQ ID NO: 4, thus only 380 amino acid residues for the polypeptide disclosed in USSN 08/585,758 vs. 390 amino acids residues in the instant SEQ ID NO: 4; (2) the parent specification need not have *ipsis verbis* support for priority.

Applicant, citing Kennecott Corporation v. Kyocera International Inc., (835 F2d 1419), argues that the instant SEQ ID NO: 4 is inherently the sequence of the isolated clone of the parent application since the separation methods, etc are all identical, even if the support of 390 amino acids does not exist in the parent application.

This argument has been fully considered but found unpersuasive. The court in Kennecott Corporation v. Kyocera International Inc., stated that the inclusion of the functional description (i.e., "equiaxed microstructure") in later filed claims does not deprive that product of the benefit of an earlier filing date.

However, the instant claim does not add an inherent functional description of a product disclosed in an earlier application. Rather, the instant claims are drawn to a new product with 10 additional amino acids with a higher molecular weight. Therefore, the instant SEQ ID NO: 4 and the SEQ ID NO: 4 in the earlier applications are two different products.

In addition, the earlier specification does not disclose how to obtain instant SEQ ID NO: 4 protein, either.

The earlier specification discloses SEQ ID NO: 3 (human tsg101 cDNA) as follows:

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US-08-585-758A-3

  Query Match             96.0%;  Score 1434;  DB 2;  Length 1494;
  Best Local Similarity   98.9%;  Pred. No. 0;
  Matches 1475;  Conservative    0;  Mismatches   12;  Indels    5;  Gaps
3;

Qy          4 GGGTGTGCGATTGTGTGGGACGGTCTGGGGCAGCCCAGCAGCGGCTGACCCTCT-GCCTG 62
              ||||||||||||||||||||||||||||||||||||   ||||||||||||   | |||||
Db          6 GGGTGTGCGATTGTGTGGGACGGTCTGGGGCAGCCA--CAGCGGCTGACCNCNTNGCCTG 63

Qy         63 CGGGGAAGGGAGTCGCCAGGCGGCCGTCATGGCGGTGTCGGAGAGCCAGCTCAAGAAAAT
122
              ||||||||||||||||||  ||||        ||||||||||||||||||||||||||||
Db         64 CGGGGAAGGGAGTCGCCAG--GGCCCGTCATCGGGTGTCGGAGAGCCAGCTCAAGAAAAT
121

Qy        123 GGTGTCCAAGTACAAATACAGAGACCTAACTGTACGTGAAACTGTCAATGTTATTACTCT
182
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        122 GGTGTCCAAGTACAAATACAGAGACCTAACTGTACGTGAAACTGTCAATGTTATTACTCT
181

Qy        183 ATACAAAGATCTCAAACCTGTTTTGGATTCATATGTTTTTAACGATGGCAGTTCCAGGGA
242
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        182 ATACAAAGATCTCAAACCTGTTTTGGATTCATATGTTTTTAACGATGGCAGTTCCAGGGA
241
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One of skilled in the art would not recognize the structure of instant SEQ ID NO: 4 protein was disclosed in the earlier specification.

Claims 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. 5,892,016 (Brie et al., 06-apr-1999).

Claims 29 and 30 are drawn to SEQ ID NO: 4 protein and pharmaceutical comprising the protein in conjunction with a suitable carrier.

Brie et al., teach an isolated protein identical to the instant SEQ ID NO: 4 (note previously provided Exhibit B).

Specification, Withdrawn

Since applicant filed a preliminary amendment to the specification on 10/29/2003 with the instant SEQ ID NO: 4 starting with M-A-V-S-E comprising 390 amino acids residues, followed by the replacement sequence listing as well as the CRF on 06/29/2004, the new matter objection to the specification is withdrawn.

Claim Rejections - 35 USC § 112, Withdrawn

The rejection of claims 29 and 30 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter) is withdrawn because (1) the preliminary amendment to the specification filed on 10/29/2003 contained the instant SEQ ID NO: 4 starting with M-A-V-S-E comprising 390 amino acids residues, followed by the replacement sequence listing as well as the CRF on 06/29/2004; and (2) the rejected claims 30 now is amended.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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